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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/743,674      | 01/10/2001  | Diawer Ala'Aldeen    | 15-840              | 5800             |

7590 08/05/2003  
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EXAMINER

DEVI, SARVAMANGALA J N

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1645

DATE MAILED: 08/05/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/743,674

Applicant(s)

Ala'Aldeen et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 58, 59, 61, 62, and 64-66 is/are objected to.
- 8) ☒ Claims 1-57, 60, 63, and 67-71 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### Lack of Unity of Invention(s)

1) Claims 4, 9-19, 21, 22, 23, 24-26, 28-39 and 41-57 have been amended via the preliminary amendment 01/10/01.

Claims 72-79 have been canceled via the preliminary amendment 01/10/01.

Claims 1-71 are under prosecution.

Claims 58 and 64-66 are not included in the lack of unity set forth below since these claims are confusing in that SEQ ID NO: 1 and/or SEQ ID NO: 3 are referred to as an amino acid sequence(s). What are Applicants trying to claim in these claims is currently not understood because the sequence listing refers to these sequences as nucleotide sequences.

Claims 59, 61 and 62 are not included in the lack of unity set forth below. Claim 59 is drawn to a 'polypeptide as claimed in claim 58'. However, claim 58 is drawn to the 'use of a polypeptide'. The same holds true with claims 62 and 61.

2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your election responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated-Fax-number-to-responses-to-Written-Restrictions.

3) The instant inventions lack unity under PCT Rule 13.1 and 13.2:

- I. Claims 1-18, drawn to a method of generating T-cell lines and clones specific to neisserial proteins, classified in class 435, subclass 372.3
- II. Claims 19-26, drawn to a method of detecting CD4+ T-cell stimulating proteins comprising fractionating neisserial proteins, classified in class 435, subclass 7.2
- III. Claims 27-39, drawn to a method of detecting CD4+ T-cell stimulating recombinant proteins comprising screening a genomic expression library, classified in class 935, subclass 80
- IV. Claims 40-57, drawn to a method of detecting CD4+ T-cell stimulating peptides

comprising screening a genomic phage display libraries, classified in class 935, subclass 58

- V. Claims 60 and 71, drawn to a DNA construct comprising SEQ ID NO: 3 or an active derivative thereof, classified in class 536, subclass 23.7
- VI. Claims 63 and 70, drawn to a DNA construct comprising SEQ ID NO: 1 or an active derivative thereof, classified in class 536, subclass 23.7
- VII. Claims 67 and part of claim 69, drawn to a vaccine comprising a polypeptide with the amino acid sequence of SEQ ID NO: 2 and a method of use of the same, classified class 424, subclass 234.1
- VIII. Claims 68 and part of claim 69, drawn to a vaccine comprising a polypeptide with the amino acid sequence of SEQ ID NO: 4 and a method of use of the same, classified class 424, subclass 249.1

4) Inventions I to VIII lack unity of invention. The special technical feature of invention I is a method of generating T-cell lines and clones specific to neisserial proteins. The special technical feature of invention II is a method of detecting CD4+ T-cell stimulating proteins comprising fractionating neisserial proteins. The special technical feature of invention III is a method of detecting CD4+ T-cell stimulating recombinant proteins comprising screening a genomic expression library. The special technical feature of invention IV is a method of detecting CD4+ T-cell stimulating peptides comprising screening a genomic phage display libraries. The special technical features of inventions V and VI are DNA constructs comprising SEQ ID NO: 3 and SEQ ID NO: 1 or an active derivative thereof, respectively. The special technical features of inventions VII and VIII are vaccines comprising SEQ ID NO: 2 and SEQ ID NO: 4 respectively and a method of using the same. The methods of inventions I, II, III and IV do not share common method steps and/or reagents. The methods of inventions V and VI and those of inventions VII and VIII do not share a common structure and/or immunogenic specificity. Furthermore, the DNA molecules of inventions V and VI are not required for the methods of inventions I through IV. Clearly, the inventions lack unity.

5) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A telephone

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message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August, 2003

  
S. DEVI, PH.D.  
PRIMARY EXAMINER